

Los Angeles County Board of Supervisors

Hilda L. Solis

December 16, 2014

First District
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Second District
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The Honorable Board of Supervisors County of Los Angeles 383 Kenneth Hahn Hall of Administration 500 West Temple Street Los Angeles, California 90012

Dear Supervisors:

pervisors COUNTY OF LOS ANGELES

17 December 16, 2014

ADOPTED

BOARD OF SUPERVISORS

PATRICK OZAWA ACTING EXECUTIVE OFFICER

Mitchell H. Katz, M.D. Director

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To ensure access to high-quality, patient-centered, cost-effective healthcare to Los Angeles County residents through direct services at DHS facilities and through collaboration with community and university partners.



SUBJECT

Approval of a Sponsored Programs Agreement with The University of Southern California as a replacement Agreement to the current research agreement with the University.

APPROVAL OF SPONSORED PROGRAMS AGREEMENT WITH THE

UNIVERSITY OF SOUTHERN CALIFORNIA

(SUPERVISORIAL DISTRICT 1) (3 VOTES)

IT IS RECOMMENDED THAT THE BOARD:

- 1. Authorize the Director of Health Services (Director), or his designee, to execute a Sponsored Programs Agreement (Agreement) with The University of Southern California (University), effective upon Board approval, with a term to continue indefinitely unless terminated by either party, for the provision of various research and non-research projects (Sponsored Programs) conducted by University at the LAC+USC Medical Center (LAC+USC MC) at no cost to County.
- 2. Delegate authority to the Director, or his designee, as required by HIPAA's Privacy Rule to execute a Data Use Agreement with Sponsored Program managers, for the use and disclosure of information in a limited data set for specified limited purposes.
- 3. Delegate authority to the Director, or his designee, to execute future amendments to the Agreement to incorporate provisions consistent with

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County ordinance, Board policy, and State/federal requirements, subject to review and approval by County Counsel, with notice to your Board and the Chief Executive Office (CEO).

PURPOSE/JUSTIFICATION OF RECOMMENDED ACTION

Approval of the first recommendation will allow the Director, or his designee, to execute an Agreement, substantially similar to Exhibit I, with University to replace the current contract for the reasons described below. Department of Health Services (DHS) and the University have a longstanding partnership whereby the University provides medical research and education projects that benefit County patients and are an integral component of the operations at LAC+USC MC.

The existing agreement enables the University to administer its medical research and education projects conducted at LAC+USC MC, and assist University researchers and educational professionals with managing their projects at LAC+USC MC. Such projects are funded by non-County sources, including, but not limited to, government and private agencies, public foundations, and individuals. The agreement also provides University with access to LAC+USC MC facilities, patients, and medical records to the extent that such access is authorized by the contract.

DHS recently determined the existing agreement did not meet the full expanse of programs which the University is conducting at LAC+USC MC and determined there was a need to put in place a more robust contract. DHS therefore re-negotiated a comprehensive replacement agreement with the University to ensure that all Sponsored Programs conducted at LAC+USC MC: 1) are aligned with DHS' mission to improve the County's health care delivery system; 2) receive approval by LAC +USC MC and as applicable, medical research committees, prior to implementation; 3) do not adversely impact the LAC+USC MC's limited resources for direct patient care; and 4) compensate LAC+USC MC for any costs related to Sponsored Program activities.

Approval of the second recommendation will ensure the confidentiality of protected health information of County patients in accordance with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and corresponding privacy regulations. In the event that a Sponsored Program manager requires a limited data set in connection with the Sponsored Program, DHS will first execute a Data Use Agreement with the Sponsored Program manager.

Approval of the third recommendation will ensure the Agreement contains provisions compliant with applicable County ordinance, Board policy, and State/federal requirements.

Implementation of Strategic Plan Goals

The recommended actions support Goal 1, Operational Effectiveness/Fiscal Sustainability, of the County's Strategic Plan.

FISCAL IMPACT/FINANCING

There is no net County Cost associated with the replacement Agreement. University will fully reimburse LAC+USC MC for any costs related to Sponsored Program activities.

FACTS AND PROVISIONS/LEGAL REQUIREMENTS

On December 16, 2003, the Board initially approved the existing agreement with Health Research

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Association, Inc. for the administration of medical research and education projects at LAC+USC MC. The Board subsequently approved an amendment to the agreement to extend the term indefinitely until terminated by either party, and delegated authority to the Director to update County standard provisions and amend the scope of work to address operational modifications.

On June 24, 2014, the Department exercised its delegated authority, approved by the Board on June 12, 2007, to execute an amendment to the agreement with Health Research Association, Inc. for an assignment and delegation to the University with the expressed intent of both parties to replace the agreement in its entirety by the end of this year.

The Agreement includes all Board of Supervisors' required provisions, including the most recent provision, "Time Off for Voting." The Agreement may be terminated for convenience by either party with prior written notice, and requires each party to indemnify the other party for all liability that may arise from Sponsored Program services provided under the Agreement.

County Counsel has approved Exhibit I as to form.

CONTRACTING PROCESS

The recommended Agreement is a replacement of a current agreement that sets forth updated terms of the provision of Sponsored Programs at LAC+USC MC. The University's work under this Agreement is not appropriate for a competitive solicitation.

IMPACT ON CURRENT SERVICES (OR PROJECTS)

Approval of the recommendations will ensure continuation of Sponsored Program projects and activities at LAC+USC MC under a more comprehensive contract with the University.

Respectfully submitted,

Mitchell H. Katz, M.D.

Director

MHK:ck

Enclosures

c: Chief Executive Office County Counsel Executive Office, Board of Supervisors

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SPONSORED PROGRAMS AGREEMENT

By and Between

The University of Southern California

And

The County of Los Angeles

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SPONSORED PROGRAMS AGREEMENT

BY AND BETWEEN

THE UNIVERSITY OF SOUTHERN CALIFORNIA

AND

THE COUNTY OF LOS ANGELES

This Agreen	nent is en	tered int	o this	day of .		,	2014 (the '	Effe	ective Date	e"), by and
between the	County	of Los	Angeles	("County")	and	The	University	of	Southern	California
("University	").									

WHEREAS, County, in furtherance of its statutory obligation to provide health care services to County residents, has established and operates an accredited hospital and clinic system and graduate medical education program at Los Angeles County + University of Southern California Medical Center (Hospital) in .partnership with University; and

WHEREAS, University conducts projects and activities at that involve direct contact with Hospital patients, access to their personal health information, and/or utilization of Hospital services and resources, originate through University or its Workforce Members, and are herein considered "Sponsored Programs" which are funded, in whole or in part, by non-County agencies including University, organizations, or individuals; and

WHEREAS, a former affiliate of University, known as Health Research Association, Inc. ("HRA"), historically assisted County by administering medical research and education services at Hospital under a contract with County; which contract was assigned and delegated by HRA to University; and

WHEREAS, the Parties now wish to enter into a new comprehensive agreement to ensure that all Sponsored Programs are aligned with the Hospital's mission to improve the County's health care delivery system, and prior to implementation, that Sponsored Programs receive Hospital approval, and all Sponsored Programs comply with applicable governmental regulations, and Hospital is compensated for any costs related to Sponsored Program activities that are not part of standard care, and

WHEREAS, this Agreement is authorized by California Health and Safety Code § 1441 and Government Code § 26227.

NOW THEREFORE, the Parties hereto agree that University and its Workforce Members may implement and perform Sponsored Program activities at Hospital pursuant to the terms of this Agreement.

1.0 **DEFINITIONS**

- 1.1. **Affiliation Agreement.** The Affiliation Agreement between the Parties dated August 1, 2006, as amended.
- 1.2. **Agreement**. This Agreement made between County of Los Angeles and University, including any Exhibits, as may be amended from time to time.
- 1.3. **Ancillary Services and Supplies**. Ancillary services and supplies, other than room, board, medical and nursing services, includes services and supplies provided to Hospital patient, which may include, but are not limited to, laboratory, radiology, pharmacy, and physical therapy.
- 1.4. **Business Associate** has the same meaning as the term "business associate" in 45 C.F.R. 160.103.
- 1.5. **CEO**. The Chief Executive Officer of Hospital, or his or her designee.
- 1.6. **CMO**. The Chief Medical Officer of the Hospital, or his or her designee.
- 1.7. **CMS**. Centers for Medicare and Medicaid Services.
- 1.8. **Common Rule**. U.S. Department of Health and Human Services (HHS) Common Rule for the protection of human subjects in Research, codified at 45 CFR 46.101
- 1.9. **County**. The County of Los Angeles, including as appropriate its departments, facilities and officials.
- 1.10. **Covered Entity.** Shall have the same meaning as the term "covered entity" in 45 C.F.R. 160.103.
- 1.11. **Data Use Agreement**. An agreement required by HIPAA's privacy rules between a covered entity and a person or entity that receives a limited data set. The Data Use Agreement must state at a minimum that the recipient will use or disclose the information in the limited data set only for specific limited purposes as set forth in DHS Policy No. 361.19 (De-identification of Protected Health Information/Limited Data Sets) and DHS Policy No. 361.27 (Use and Disclosure of Protected Health Information for Research Purposes) as in effect at any given time.
- 1.12. **Department of Health Services (DHS)**. The County of Los Angeles Department of Health Services.
- 1.13. **DHS Research Committee.** A committee or designee responsible for overseeing Hospital's approved list of research projects, with discussion and review of select project requests flagged by the Hospital or one of the committee members
- 1.14. **Director**. The Director of the County of Los Angeles Department of Health Services, or his or her designee.

- 1.15. **FDA**. U.S. Food and Drug Administration.
- 1.16. **Federalwide Assurance**. Assurance filed with the Office of Human Research Protections ("OHRP") within the US Department of Health & Human Services ("HHS") in compliance with 45 CFR part 46.
- 1.17. **Governing Board**. The Los Angeles County Board of Supervisors.
- 1.18. **HIPAA**. Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a federal legislation with several provisions. HIPAA provides protections to patients with respect to the privacy of their medical records. HIPAA Title II includes an administrative simplification section which deals with the standardization of healthcare-related information systems. HIPAA Title II seeks to establish standardized mechanisms for electronic data interchange, security, and confidentiality of all healthcare-related data. If an agreement is made with another agency for services at that agency, a Business Associates Addendum or Business Associates Agreement may be required to ensure the maximum security of the protected health information.
- 1.19. **Hospital**. The Los Angeles County + University of Southern California Medical Center, including all inpatient departments, ancillary services, and outpatient clinics.
- 1.20. **Hospital Bylaws and Policies**. Hospital's medical staff bylaws, medical staff rules and regulations and all policies and procedures adopted by Hospital, as in effect from time to time, to govern the provision of patient care, ethics, occupational health, fire safety, infection control, health information privacy and Sponsored Program compliance.
- 1.21. **Informed Consent**. Informed consent means the knowing consent of an individual (or of a legally authorized representative when a vulnerable or dependent person is to be involved) to his or her participation in a Sponsored Program activity without coercion or undue influence. Consent information, oral or written, must be expressed with words and in a language which is understandable to the Sponsored Program Subject or the representative. The text of the consent information must not involve any exculpatory language through which the Sponsored Program Subject is made to waive, or to appear to waive, any legal rights, including release of University or its agents from liability for negligence. All Sponsored Program Subjects or their authorized representatives must receive a copy of any consent document which has been completed by them.
- 1.22. **Institutional Review Board (IRB)**. Institutional review board designated in Hospital's Federalwide Assurance, including any other duly designated IRB.
- 1.24 **Medicare Coverage Analysis (MCA)** is a detailed review required by Medicare of clinical research items, services, procedures and Medicare billing rules to determine the appropriate payer/funding source for each item or service.
- 1.25. **Organized Health Care Arrangement** shall have the same meaning as "Organized Health Care Arrangement as contained in 45 CFR §160.103.

- 1.26. **Party or Parties**. County or University, or both, as appropriate.
- 1.27. **Principal Investigator (PI)**. Principal investigator is a person authorized by University who takes direct responsibility for completion of a Sponsored Program project, directing the Sponsored Program, and reporting directly to the funding agency.
- 1.28. **Research.** A systematic, intensive Sponsored Program intended to increase knowledge or understanding of the subject studied, a systematic Sponsored Program specifically directed toward applying new knowledge to meet a recognized need, or a systematic application of knowledge to the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.
- 1.29. **Research Orders.** A template set of medical orders that will be developed in collaboration with Hospital, for each Sponsored Program, using a format that is mutually agreed upon by Hospital and University and that may change from time to time. Sponsored Program Manager and Workforce Members must use County Research Orders to request Hospital Services, Ancillary Services or Supplies during the conduct of a Sponsored Program.
- 1.30. **Sponsored Program**. Sponsored Program is a program that receives grants, contracts, gifts, and/or other means of financial assistance in the form of money, property, or both in order to carry out a project or activity under this Agreement, and may be originated by University or by one of its Workforce Members. Such programs may or may not include research.
- 1.31. **Sponsored Agreement.** An agreement between University and third parties governing Sponsored Program activities.
- 1.32. **Sponsored Program Manager.** Sponsored Program Manager is a Workforce Member, whom University has designated to administer and oversee a Sponsored Program, which could include the Principal Investigator or grant manager or other persons deemed appropriate by University. If any Sponsored Program involves Sponsored Program Subjects, the Sponsored Program Manager shall have appropriate licenses and certifications.
- 1.33. **Sponsored Program Services**. Administrative and clinical services that Hospital offers under this Agreement.
- 1.34. **Sponsored Program Subject**. A living person participating in a Sponsored Program which obtains (a) data through intervention or interaction with the person, or (b) identifiable private information. A person may be a human subject when a Sponsored Program obtains data about the person from a third party or from the person directly. A Sponsored Program Subject is a person recruited by the Sponsored Program to participate in a Sponsored Program, and may or may not be a patient who receives medical care at Hospital.

- 1.35. **Term.** Term shall have the meaning ascribed to it in Section 5.1.
- 1.36. **The Joint Commission.** Formerly known as "The Joint Commission on Accreditation of Healthcare Organizations," is the accrediting body for health care facilities, or any successor organization.
- 1.37. **University**. The University of Southern California.
- 1.38. **Workforce Members.** Workforce Members are defined as employees, contractors, volunteers, trainees, students and other persons, whether or not they are paid, whose conduct, is under the direct control of University to perform or complete work under this Agreement.

2.0 UNIVERSITY RESPONSIBILITIES

- 2.1. University shall provide Hospital with a listing of the title, University IRB number, and Sponsored Program Manager of all Sponsored Programs originated by University and/or its Workforce Members, and conducted at Hospital at the time of execution of this contract and on a monthly basis thereafter. University will provide Hospital, through CMO, with access to IRB or information relevant to Sponsored Program. Sponsored Programs may or may not include Research, and therefore, must be disclosed to CMO.
- 2.2. University will obtain the review and approval by CMO and as applicable, DHS Research Committee of all University proposed Sponsored Programs that seek to use Hospital facilities and/or resources prior to initiating such programs at Hospital facilities or with Hospital Resources. University will notify CMO when a Sponsored Program that proposes to utilize Hospital patients, their personal health information, or Hospital resources is submitted for review by University IRB. University will provide CMO access to IRB files for all such Sponsored Programs for purposes of review, as described in Section 3.1. CMO will notify University when a Sponsored Program has received final clearance by Hospital. For sponsored programs not requiring IRB review, University shall also provide CMO access to the sponsored program description for all other Sponsored Programs.
- 2.3 University will allow CMO to send representative(s) to meetings of University's Health Sciences IRB for purposes of gaining information on Sponsored Programs that are proposing to use Hospital Services, Ancillary Services or Supplies. University should be notified and given the opportunity to review and approve the appointment of any proposed representatives.
- 2.4. University will comply with the Common Rule, as applicable to all Sponsored Programs involving human subjects, as defined by Common Rule, for which University is responsible, regardless of the source of funding or whether the Sponsored Program is funded. In the case of conflict between regulations of the funding or regulatory agency and HHS, the more restrictive regulations shall prevail. The University is also obligated by law to adhere to the regulations of the FDA (21 CFR 50.1 and 56.101) governing Sponsored Programs involving investigational new drugs [within the meaning of 21 U.S.C. sections 355(i)(j)], or investigational new devices [within the meaning of 21 U.S.C. section 360(g)].

- 2.5. University shall ensure that all University Sponsored Program Workforce Members have the necessary licenses and certifications for Sponsored Program related activity, and have appropriate and current credentials, reported to University human resources department, to assure safe and competent Sponsored Programs.
- 2.6. **Requirements for Sponsored Programs**. University will conduct Sponsored Programs at Hospital, and such Sponsored Programs will be led by a Workforce Member.
 - 2.6.1. The Sponsored Program Manager will have overall responsibility for the Sponsored Program; provided that subject to specific Sponsored Program Services requirements, University policy (e.g. conflicts of interest in research), and/or as applicable, the requirements of 21 CFR § 54, the Sponsored Program Manager may be required to delegate some of his/her responsibilities to other qualified Workforce Members.
 - 2.6.2. Sponsored Program Managers who have obtained final clearance from University IRB and have been given access to Hospital approved Research Orders for a Sponsored Program may refer Sponsored Program Subjects to Hospital for clinical services or request use of Hospital's diagnostic, therapeutic, and ancillary resources. Hospital retains sole discretion to prioritize access to its clinical, diagnostic, therapeutic, and Ancillary Services and Supplies.
 - 2.6.3. University will notify Hospital promptly of any change in a Sponsored Program Manager.
 - 2.6.4 As applicable, prior to initiation of a Sponsored Program at Hospital, University will create and provide Hospital with access to University's Medicare Coverage Analysis (MCA) to allow County to develop its Research Orders for the Sponsored Program. In such MCA, University shall make good faith efforts to correctly apply Medicare's rules regarding coverage and payment for services provided to Medicare beneficiaries who are participating in Sponsored Programs involving clinical trials, and shall designate in the MCA which services, if any, University believes are covered by Medicare. Sponsored Program Manager and other Workforce Members will be required to use the County's Research Order or other appropriate documentation as mutually agreed to and developed by both Parties to request Sponsored Program Services and/or supplies from Hospital during the conduct of the Sponsored Program.

Hospital is responsible for billing Medicare and other third party payers, consistently with the Research Orders. University shall pay Hospital for Sponsored Program Services and/or supplies, which are not routine care and which the patient would not have received absent their participation in a Sponsored Program. Hospital will bill University and University will reimburse Hospital for the cost of such non-routine care Sponsored Program Services and/or supplies which the patient would not have received absent their participation in a Sponsored Program. Hospital shall have sole responsibility, and any and all liability, for the accuracy of coding determinations and information included on claims submitted by Hospital to Medicare and other third party payers. Hospital will maintain and make available upon request by University

- accurate and appropriate documentation to support all Sponsored Program related claims submitted to University.
- 2.6.5. <u>Informed Consent</u>. The Sponsored Program Manager will obtain Sponsored Program Subject's Informed Consent that complies with requirements set forth in 45 CFR, Part 46, Subpart A (Section 46.116); and 21 CFR, Part 50 (Sections 50.20 and 50.25) and California Health and Safety Code Section 24172.
- 2.7. **Other Sponsored Program Staff Workforce Members**. University will ensure that adequate numbers of qualified Workforce Members are assigned to each Sponsored Program.
- 2.8. **Compliance.** The Sponsored Program Manager and all University Workforce Members will comply with the University policies and regulations, Hospital Bylaws and Policies, as applicable, related to Sponsored Program activity at Hospital. In addition, to the extent that federal or State law, or both, require additional approval(s) by federal or State agencies, or by others for the conduct of certain Sponsored Programs, University shall assist Sponsored Program Managers in assuring that such approval(s) shall be obtained. The Parties contemplate and intend that any clinical Sponsored Programs that receive such approval may be conducted by Sponsored Program Manager and Workforce Members at Hospital subject to the terms contained herein. Sponsored Programs that do not comply with all applicable, University, Hospital, federal, and State policies and regulations will be considered as Unauthorized Sponsored Programs. Unauthorized Sponsored Programs are unacceptable and will result in immediate termination of Sponsored Program Manager's ability to perform any Sponsored Program at Hospital until further analysis by CMO and as applicable, DHS Research Committee. University will be subject to suspension or termination of the Sponsored Program at Hospital.
- 2.9. Access. County shall grant University and, as well as Sponsored Program Workforce Members, access to Hospital's (1) facility, (2) personnel, to the extent that access to personnel is authorized (3) patients, medical records and other information required for Hospital to provide Sponsored Program Services for, as well as for Sponsored Program Workforce Members to conduct, in accordance with professional standards, for Sponsored Programs and (4) other services, equipment, supplies and resources of Hospital, as such items will be provided by County in accordance with the terms set forth in the this Agreement. The scope of the access granted under this Agreement shall be subject to compliance with applicable laws, rules and regulations and limited to the extent reasonably required by University to perform Sponsored Program activities, as further described hereunder. County does not authorize nor permit Workforce Members to add, delete, copy, transfer, or otherwise take possession or store in either a paper or electronic format any Hospital patient's medical record without prior approval of Hospital and unless the Sponsored Program Manager(s) and Hospital have entered into a Data Use Agreement. When needed, the parties will enter into a mutually acceptable Data Use Agreement.
- 2.10. **Utilization of County Personnel**. Except as included in the cost of Hospital Services, Ancillary Services or Supplies requested through Research Orders or with written approval by CMO and/or expressly authorized under the terms of this Agreement, County employees while on County time shall not be utilized by University in the performance of its services hereunder.

2.11. **Sponsored Program Performance**.

- 2.11.1. University will (and will cause the Sponsored Program Manager to) conduct the Sponsored Program in accordance with this Agreement, the applicable IRB-approved protocol (as amended from time to time), all IRB requirements, all reasonable written instructions of the sponsor (if any), and all applicable laws, regulations and standards; provided, however, the Sponsored Program Manager may deviate from the protocol and such instructions to the extent that the safety, rights and welfare of Sponsored Program Subjects so requires.
- 2.11.2. Sponsored Programs will commence at Hospital only when the Sponsored Program has received approvals from University's IRB and, when applicable, CMO, and DHS Research Committee, including any other approvals required by Hospital.

2.12. Records and Reporting.

- 2.12.1. Sponsored Program Records. The Sponsored Program Manager will create and maintain records, including case report forms for all Sponsored Program Subjects, in the manner and for the time periods required by the Sponsored Program protocol or Sponsor and all state and federal laws and regulations applicable to the Sponsored Program. For studies utilizing Hospital facilities, the Sponsored Program Manager will make such records available to CMO as needed for compliance monitoring to the extent that such records do not contain confidential or proprietary information.
- 2.12.2. Medical Records. For Sponsored Programs that involve a clinical treatment or diagnostic intervention with Sponsored Program Subjects, the Sponsored Program Manager will place the following in each Sponsored Program Subject's clinical file, in a manner that complies with the applicable requirements of Hospital and The Joint Commission, licensing authorities, CMS and other state and federal laws and regulatory standards:
 - a copy of the Sponsored Program Subject's signed Informed Consent form and HIPAA authorization, if required by the IRB (unless Informed Consent form is labeled "DO NOT PLACE IN MEDICAL RECORD");
 - a medical record note of enrollment in named Sponsored Program;
 - a list of any medication(s) administered as part of a Sponsored Program; and
 - notes needed for communication to primary provider care to assure continued safe clinical care, which required notes would be ordered on the Research Orders.

Inclusion of this information in the file does not necessarily imply inclusion in the legal health record or designated record set, which is determined by each institution's policies. The Parties will cooperate to ensure compliance with applicable law and guidance, including but not limited to HIPAA and its implementing regulations, with regard to restriction of Sponsored Program Subjects' access to records during a Sponsored Program and disclosure of records,

- 2.12.3. Reports. The Sponsored Program Manager will do the following:
 - report adverse events as defined by University's IRB adverse event reporting
 procedures, in accordance with Hospital Bylaws and Policies, and if
 applicable, to Hospital's electronic reporting system for clinical errors or
 safety risk events.
 - provide the names and medical record numbers of Sponsored Program Subjects at intervals consistent with Hospital Bylaws and Policies.

2.13. Acknowledgement and Attribution of Hospital's Contribution

- 2.13.1. To the extent feasible, investigators whose Sponsored Programs are performed within Hospital in whole or in part shall acknowledge and provide appropriate attribution to Hospital in all scientific presentations and publications.
- 2.13.2. To the extent feasible, University and Hospital will jointly prepare any media press release/advisory, media notification or social media content that announces the findings of any Sponsored Program conducted at Hospital in accordance with the Sponsored Agreement.
- 2.13.3 University and Sponsored Program Managers reserve the sole right to publish scientific papers in connection with its Sponsored Programs to the extent authorized by federal and State law.
- 2.14. **Sponsored Program Closeout**. For studies utilizing Sponsored Program Services or Ancillary Services and Supplies, University shall notify CMO at the time that a Sponsored Program is closed or completed.

2.15. Sponsored Program Contract Provisions.

- 2.15.1. Hospital Not Bound. University acknowledges that Hospital will not be bound by provisions in Sponsored Program agreements to which it is not a party, unless County has an opportunity to review such provisions and agrees to them in writing.
- 2.16. **Debarment and Disqualification**. University will not knowingly allow any individual who appears on the FDA Debarment List, is disqualified or restricted as a clinical investigator by the FDA or appears on the Public Health Service Administrative Actions List to provide services related to the Sponsored Program. University further represents and warrants that University personnel have not been found by the FDA or any other state or federal government agency or enforcement body to have violated any federal, state or local laws, rules or regulations relating to the Sponsored Program. If University becomes aware of any relevant disbarment or restriction during the Term, or comes under investigation for conduct related to any Sponsored Program, University shall promptly notify Hospital.
- 2.17. **General Insurance Requirements**. Without limiting University's indemnification of County and during the term of this Agreement, University shall provide and maintain, and shall require all of its subcontractors to maintain, the following programs of insurance specified in this Agreement. Such insurance shall be primary to and not contributing with any other insurance or self-insurance programs maintained by County, and such coverage

shall be provided and maintained at University's own expense. In any event, University may satisfy the insurance coverage requirements specified in this Agreement by providing evidence of University's self-insurance program, as described hereinbelow. Such evidence shall be provided in a formal declaration (on University's letterhead, if available) that declares University is self-insured for the type and amount of coverage as described in Section 2.18, Insurance Coverage Requirements, hereinbelow. University's declaration may be in the form of a corporate resolution or a certified statement from a corporate officer or an authorized principal of University. The statement also must identify which required coverages are self-insured and which are commercially insured. If University is self-insured for workers compensation, University must provide a copy of their "Certificate of Intent to Self-Insure" issued by the state in which services will be provided. Further, University's self-insurance program must be reviewed and approved by County's Risk Manager prior to the effective date of this Agreement.

- 2.17.1 Evidence of Insurance: Certificate(s) or other evidence of coverage satisfactory to County shall be delivered to Director at the: Department of Health Services; Contracts and Grants Division; 313 North Figueroa Street, 6th Floor-East; Los Angeles, California 90012-2659, and to LAC+USC Medical Center; Administration; 1200 North State Street, Room 1112; Los Angeles, California 90033; prior to commencing services under this Agreement. Such certificates or other evidence shall:
 - 2.17.1.1 Specifically identify this Agreement
 - 2.17.1.2 Clearly evidence all coverages required in this Agreement.
 - 2.17.1.3 Contain the express condition that County is to be given written notice by University, to be sent by mail at least thirty (30) calendar days in advance of cancellation for all policies evidenced on the certificate of insurance.
 - 2.17.1.4 To the extent authorized under University's insurance coverages, include copies of the additional insured endorsement to the commercial general liability policy, adding County of Los Angeles, its Special Districts, its officials, officers, and employees as insured for all activities arising from this Agreement.
 - 2.17.1.5 Identify any deductibles or self-insured retentions for County's approval. To the extent that the University's coverage is inconsistent with commercially reasonable standards and the financial position of University, as determined in County 's reasonable discretion, County retains the right to require University to reduce or eliminate such deductibles or self insured retentions as they apply to County.
- 2.17.2. Insurer Financial Ratings: Except as otherwise approved by County, which approval shall not be unreasonably withheld, insurance is to be provided by an insurance company acceptable to County with an A.M. Best rating of not less than A:VII.

- 2.17.3 Failure to Maintain Coverage: Failure by University to maintain the required insurance, or to provide evidence of insurance coverage acceptable to County, shall constitute a material breach of contract upon which County may immediately terminate or suspend this Agreement. County may purchase such required insurance coverage, and without further notice to University, County may deduct the sums due to University any premium costs advanced by County for such insurance.
- 2.17.4 Notification of Incidents, Claims, or Suits. University shall report to County:
 - 2.17.4.1 Any accident or incident relating to services performed under this Agreement which involve personal injury or property damage and which may result in the filing of a claim or lawsuit against University and/or County. Such report shall be made in writing within five (5) days of University becoming aware of such incident.
 - 2.17.4.2 Any third party claim which may reasonably be expected to result in the filing of a lawsuit against University arising from or related to services performed by University under this Agreement.
 - 2.17.4.3 Any injury to a Workforce Member which occurs on County property. This report shall be submitted on a County "Non-Employee Injury Report" to County contract manager.
 - 2.17.4.4 Any loss, disappearance, destruction other than in the ordinary course of business, misuse, or theft of County property used, by University under the terms of this Agreement.
 - 2.17.4.5 Any accident or incident relating to Sponsored Programs at Hospital which involve personal injury or property damage and which may result in the filing of a claim or lawsuit against another Workforce Member, University and/or County that the University is made aware of. Such report shall be made by University promptly upon University's receipt of notice of such incidents from a Workforce Member. Notwithstanding any other language set forth herein, the obligations of University under this paragraph shall not be deemed to require University to disclose any information in violation of the requirements imposed under the bylaws, rules or regulations of Hospital or the IRB or in violation of applicable laws, rules and regulations.
- 2.17.5. Compensation for County Costs: In the event that University fails to comply with the insurance requirements of this Agreement, and such failure to comply results in any costs to County, University shall pay full compensation for all such costs incurred by County.
- 2.17.6 Insurance Coverage Requirements for Subcontractors University shall ensure any and all subcontractors performing services under this Agreement maintain insurance coverages, which are consistent with commercially reasonable standards for such subcontracts and meet the insurance requirements of this Agreement that are reasonably applicable to such subcontractor by either:

- 2.17.6.1 University providing evidence of insurance covering the activities of subcontractors, or
- 2.17.6.2 University providing evidence submitted by subcontractors evidencing that subcontractors maintain the required insurance coverage. County retains the right to obtain copies of evidence of subcontractor insurance coverage at any time.
- 2.17.6.3 Notwithstanding any other language set forth herein, subcontractors subject to, and complying with, the insurance requirements established under the Hospital's medical staff bylaws shall be deemed to be in compliance with the insurance requirements set forth under this Agreement.

2.18 Insurance Coverage Requirements

2.18.1 General Liability Insurance (written on Insurance Services Office ["ISO"] policy form "CG 00 01" or its equivalent) with limits of not less than the following:

General Aggregate: \$2 Million

Products/Completed Operations Aggregate: \$1 Million

Personal and Advertising Injury: \$1 Million

Each Occurrence: \$1 Million

- 2.18.2 Automobile Liability Insurance (written on ISO policy form "CA 00 01" or its equivalent) with a limit of liability of not less than \$1 Million for each accident. Such insurance shall include coverage for all "owned", "hired" and "non-owned" vehicles, or coverage for "any auto."
- 2.18.3 Workers Compensation and Employers' Liability insurance providing workers compensation benefits, as required by the Labor Code of the State of California or by any other state, and for which University is responsible.
- 2.18.4. For claims solely related to Research services, which do not involve services that are typically provided absent a clinical trial, USC shall provide Professional Liability Insurance covering liability arising from any error, omission, negligent or wrongful act of University, or its officers or employees with limits of not less than \$1 Million per occurrence and \$3 Million aggregate. In order to facilitate University's compliance with its obligations under this Section, County shall reasonably cooperate with University regarding participation in the County's professional liability insurance coverage and/or programs of self" insurance for professional liability. Such participation of University may be on terms similar to those offered to other management service providers similar to University.

2.18.5 Hospital's Insurance Coverage. Without limiting County's indemnification obligations under this Agreement, County shall provide and-maintain insurance coverages and/or programs of self-insurance which are consistent with industry standards and the levels of insurance maintained by other similar county hospitals

3.0 COUNTY RESPONSIBILITIES

- 3.1. **Institutional Approval of Sponsored Program Applications**. CMO and as applicable, DHS Research Committee, will review all Sponsored Program proposals that seek to use Hospital facilities in accordance with Hospital's policies and procedures. Unless CMO or DHS Research Committee determines otherwise, a Sponsored Program will be considered approved for initiation at Hospital when it has full clearance from University IRB and when it has been given access to Hospital Approved Research Orders. CMO will establish a review process for all other Sponsored Programs (e.g. non-research and education) to evaluate such programs' alignment with Hospital's mission, impact on Hospital resources, and other related considerations prior to approving it implementation at Hospital.
- 3.2 Review by CMO and as applicable, DHS Research Committee: Within three-weeks prior notification by University that a new Sponsored Program requiring full IRB review is being proposed for conduct at Hospital, Hospital will notify University if a review of a Sponsored Program will be conducted by CMO or as applicable, DHS Research Committee. Hospital will notify University of the outcome of the review within ten (10) business days thereafter. Approval by CMO and as applicable, DHS Research Committee, will be required by University IRB or University grant manager for final clearance of such studies by University IRB or University grant manager. CMO approval will be deemed granted if the timelines for review and approval in this Section are not met by Hospital or CMO.
- 3.3 **Debarment and Disqualification**. County and University will ensure that their Workforce Members do not knowingly include any individual to who appears on the FDA Debarment List, is disqualified or restricted as a clinical investigator by the FDA or appears on the Public Health Service Administrative Actions List to provide services related to the Sponsored Program.
- 3.4. **Collaborative Sponsored Program Practice Development**. Hospital may include representatives of University in all planning activities and standing committees that will involve Sponsored Programs conducted by University Workforce Members within Hospital facilities.

3.5. County's Obligation for Future Fiscal Years.

Notwithstanding any other provision of this Agreement, County shall not be obligated under this Agreement, during any fiscal year of County commencing on or subsequent to date of execution of this agreement, unless and until the Governing Board appropriates funds for the operation of Hospital in County's Budget for each such future fiscal year. In the event that funds are not appropriated for the operation of the Hospital, or the appropriation of funds contemplates that the operations of the Hospital will be materially modified in a manner that makes the performance of this Agreement impractical, then this Agreement shall be deemed to have terminated on June 30th of the last County fiscal year for which funds were

- appropriated. The Director shall notify University in writing of such non-appropriation of funds at the earliest possible date.
- 3.6. **Hospital's Insurance Coverage**. Without limiting County's indemnification obligations under this Agreement, County shall provide and maintain insurance coverages and/or programs of self-insurance which are consistent with industry standards and the levels of insurance maintained by other similar county hospitals

4.0 BILLING AND REIMBURSEMENT

4.1. **Payment to Hospital**.

- 4.1.1. University shall pay Hospital for Sponsored Program costs incurred by Hospital that are related to Sponsored Program Services and/or supplies, which patient would not have received absent their participating in a Sponsored Program. University shall reimburse Hospital for the costs of such Sponsored Program Services and/or supplies at the charge rates approved by the Governing Board. Upon execution of this Agreement, Hospital shall send University an electronic copy or, if both Parties agree, a hard copy of its current charge rates, including any modification of such rates as may be approved by the Governing Board from time to time. The terms of this §4.1 (payment to Hospital) shall survive termination of this Agreement with respect to contracted services rendered during the Term.
- 4.1.2. Hospital will bill the University within one year or earlier upon notification by University requesting an expedited billing after the Sponsored Program Services and/or supplies were provided to the Sponsored Program participants in accordance with DHS' Board-approved billing rates in effect at the time that such Sponsored Program Services and/or supplies were provided by Hospital.
- 4.1.3. Payment by University to Hospital hereunder shall be made within one hundred eighty (180) days after receipt of an invoice and billing statement. University will be responsible for payment to Hospital for all Sponsored Program Services and/or supplies that the Sponsored Program Subjects receive that are not routine care and which such subjects would not have received absent their participation in a Sponsored Program. Such services and/or supplies must be ordered on a Hospital approved Research Order or other appropriate documentation as mutually agreed to and developed by both Parties.
- 4.1.4. University and Hospital will jointly work to ensure appropriate reimbursement occurs in compliance with this Agreement and legal requirements, including Stark and Anti-Kickback. University will be responsible for payment to Hospital for nonroutine Sponsored Program Services and/or supplies provided by Hospital which the patient would not have received absent their participation in a Sponsored Program, whether or not University has received funding or corresponding payment from the sponsor.
- 4.2. **Sponsored Program Subject Billing**. The University is responsible to provide Hospital with MCA and the Hospital is responsible to ensure Sponsored Program Subject's payer

- source is not billed for any tests or procedures that are identified as payable by Sponsor Program's MCA.
- 4.3. **Compliance with Deficit Reduction Act of 2005**. Each Party represents that the compensation provided under this Agreement represents the fair market value of the Sponsored Program Services performed by Hospital, has been negotiated in an arm's-length transaction, and has not been determined in any manner with regard to the value or volume of any business or referrals generated.

5.0 TERM AND TERMINATION

- 5.1. **Term.** The term of this Agreement shall commence on the "Effective Date" and shall continue in full force and effect, unless otherwise terminated in accordance with the provisions herein.
- 5.2. **Preservation of Other Remedies.** Failure of non-breaching Party to elect termination under the provisions of this section shall not constitute a waiver of other remedies.
- 5.3. **Immediate Termination**. The following shall constitute events of immediate termination, and the non-breaching Party may terminate this Agreement immediately upon providing written notice of breach and immediate termination, or upon such other date as provided in the notice.
 - 5.3.1. Patient Safety. Notwithstanding Section 5.7, an incident arises involving the provision (or lack thereof) of Sponsored Program Services by Workforce Members which is deemed by the County to be detrimental to patient safety, or a determination by the County that such termination is in the best interest of patient safety and security. Such termination may be in whole or in part provided that County has notified University of the incident and provided the University with an opportunity to cure.
 - 5.3.2. <u>Destruction of Premises</u>. Whole or partial destruction during the term of this Agreement of County Facilities by casualty, if Parties agree that it is thereby rendered unsuitable for the provision of Sponsored Program Services as contemplated, and other suitable facilities are not reasonably available.
 - 5.3.3. Improper Consideration. The offer or provision of consideration in any form by University, either directly or through an intermediary, to any County officer, employee or agent with the intent of securing this Agreement or securing favorable treatment with respect to the award, amendment or extension of the Agreement or the making of any determinations with respect to University's performance pursuant to this Agreement. Such improper consideration, among other items, may take the form of cash, discounts, service, the provision of travel or entertainment, or tangible gifts. University shall report any attempt by a County officer or employee to solicit improper consideration for such purposes immediately upon becoming aware of any such attempt. The report shall be made either to County's manager charged with the supervision of the employee or the County Auditor-Controller's Employee Fraud Hotline (currently 213/974-0914 or 800/544-6861).

- 5.3.4. Other Events. Violation of this agreement of §2.20 (insurance coverage requirements), §8.7 (nondiscrimination in employment), §8.15 (subcontracting), §8.27 (County lobbyists), or violation of University's obligations under §4.1 (payment to Hospital).
- 5.4. **Termination for Default**. This Agreement may be terminated by either Party in the event that the other Party breaches the material terms of this Agreement and fails to cure any such breach within a) ten (10) business day period, or such longer period as approved in writing by the non-breaching Party, following receipt of notice from the non-breaching Party regarding such breach. The non-breaching Party's failure to exercise this right of termination shall not constitute a waiver of such right, which may be exercised at any subsequent time. Without limiting the generality of the foregoing, failure of University to maintain compliance with the requirements set forth in this §5.4 (termination for default) shall constitute default under this Agreement. Without limiting the rights and remedies available to County under any other provision of this Agreement, failure of University to cure such default within ten (10) business days of notice, or such longer period as approved in writing by County, shall be grounds upon which county may terminate this Agreement.
- 5.5. **Termination for Convenience**: The performance of services under this Agreement may be terminated with or without cause in whole or in part at any time when such action is deemed by County to be in its best interest upon one year advance notice specifying the extent to which performance of services under this Agreement is terminated and the date upon which such termination becomes effective.
- 5.6. **Termination of Services by University**. Notwithstanding anything to the contrary, University may terminate the provision of services with respect to any Sponsored Program immediately upon: (1) written notice to County upon University's or the Hospital's IRB's identification of any medical risk to Sponsored Program Subjects, as applicable; (2) receipt of notice of regulatory action by the FDA terminating or suspending that medical Research Sponsored Program; or (3) termination of the Sponsored Program by the Sponsor. County shall inform University immediately in the event that County determines that any Sponsored Program safety concern exists so that University may determine whether termination is appropriate. In addition, University may terminate this Agreement at any time, without cause, upon ninety (90) days prior written notice to County.
- 5.7. **Suspension of Sponsored Program by CMO**. Notwithstanding Section 5.3.1, in the event CMO finds that any activity conducted by Workforce Members at Hospital endangers the health or safety of County patients, County personnel, or others, University shall request such Workforce Members to suspend such activity immediately upon University's receipt of a written notice from CMO. In addition, University shall agree that CMO may close or secure the premises where the activity has been conducted until such time as the activity is reasonably determined to be safe or, when hazardous, until such time that the premises are reasonably determined to be non-hazardous to County patients, County workers, and others.
- 5.8 <u>Survival</u>. The following provisions of this Agreement shall survive its termination and expiration: §7.0 (indemnification), §2.19 (general insurance requirements, §2.20 (insurance coverage requirements), §6.2 (records and audit), §8.2 (confidentiality), §8.15

(subcontracting), §8.24 (indemnification for fair labor standards), §8.25 (indemnification for employment eligibility verification), and §8.31 (investigations).

6.0 REPORTING AND ACCOUNTABILITY

6.1. **General Operations.** Each Party shall collect and maintain accurate information on the nature and scope of its operations in County facilities and provide such information as reasonably requested by the other Party

6.2. Records and Audits.

- 6.2.1. <u>Financial and Time Keeping and Other Records</u>. University shall prepare and maintain accurate and complete financial and other operational/business records of the Sponsored Program Services in accordance with University policies.
- 6.2.2. Federal Access to Records. If, and to the extent that, Section 1861(v)(1)(I) of the Social Security Act [42 U.S.C. Section 1395x(v)(1)(I)] is applicable, University agrees that for a period of five (5) years following the expiration or termination of this Agreement, or as otherwise required by law, University shall maintain and make available, upon written request, to the Secretary of the United States Department of Health and Human Services or the Comptroller General of the United States, or to any of their duly authorized representatives, the contract, books, documents and records of University which are necessary to verify the nature and extent of the cost of services provided hereunder. Furthermore, if University carries out any of the services provided hereunder through any subcontract with a value or cost of Ten Thousand Dollars (\$10,000) or more over a twelve-month period with a related organization (as that term is defined under Federal law), University agrees that each such subcontract shall provide for such access to the subcontract, books, documents and records of the subcontractor. In the event that such request for access is made by any representative of the Federal government, University shall notify County in writing within five (5) business days of receipt of such request.
- 6.2.3. Audit Reports. In the event that any Federal or State auditor conducts an audit of University and such audit directly concerns or has a material effect on any of the Sponsored Program Services, University shall file a copy of any final audit report prepared by such auditor with County's Auditor-Controller within thirty (30) days of receipt thereof to the extent permitted under this Agreement, or under applicable State or Federal law or regulations.
- 6.2.4. <u>Audit/Compliance Review</u>. During the Term or within five (5) years after expiration or termination of this Agreement, authorized representatives of County may conduct an audit, upon advance written notice, during normal business hours, of University's performance of the services provided under this Agreement. In the event County representatives conduct an audit/compliance review of University, University shall cooperate fully with County's representatives. University shall allow County representatives reasonable access to all non attorney/client privileged records of services rendered and all financial, medical and other records that directly concern or may have a material effect on services provided by University under this Agreement

and shall allow photocopies to be made of these documents using University's photocopier, for which County shall reimburse University promptly for its customary charge for record copying services, if requested. Information obtained through an audit/compliance review shall be subject to the confidentiality requirements of §8.2 (Confidentiality). County shall provide University with at least fifteen (15) working days prior written notice of any audit/compliance review.

University shall have the opportunity to review County's audit findings, and University shall have thirty (30) days after receipt of County's audit/compliance review results to submit documentation to County to resolve any audit exceptions. For any audit exceptions unresolved to County's reasonable satisfaction following this thirty (30) day period, County may apply the exception rate found in the audit or statistical sample of University's total payment to County. If University chooses to appeal County's application of an audit exception rate under this §6.2.4 (audit/compliance review), University shall submit documentation for review by the Director within thirty (30) days after application of the exception rate.

- 6.2.5. Audit Settlements. Nothing in this Agreement shall restrict the right of County or University to pursue any claims for repayment or additional payment based on the results of an audit/compliance review conducted under §6.2.4 (audit/compliance review). In the event any third-party reimbursement to County, whether by Medicare, Medi-Cal, Medi-Cal/Short Doyle, private or other payers, is denied or reduced due to University's failure to provide the documents set forth in this Agreement for a period of five (5) years following the expiration or termination of this Agreement, University shall indemnify County for such losses. Such losses include denial or reduction with respect to individual claims, cost report disallowances, or others.
- 6.2.6. <u>Failure to Comply</u>. Failure of University to comply with the provisions of this §6.2 (records and audits) shall constitute a material breach of this Agreement. If such breach is not remedied within ninety (90) days following receipt of written notice from County, then it shall become an event of termination for cause pursuant to §5.4 (termination for cause).
- 6.2.7. <u>Inspection</u>: If any governmental or regulatory authority notifies Hospital that the authority will, in connection with Sponsored Programs at the Hospital, inspect Hospital's records, facilities, equipment or procedures, or otherwise take action related to the Sponsored Program, County shall promptly notify University and allow University representatives to be present at the inspection/action and participate in any response to the inspection/action to the extent permitted by law. County shall provide University with copies of any reports issued by the authority and County's proposed response.
- 6.2.8. Review Rights: In order to ensure compliance with this Agreement and any Sponsor Agreements, University may need access to information maintained by County. Upon request by authorized University personnel, County shall provide to University, in a timely manner as mutually agreed by the parties, access to records for any Sponsored Program Subjects for whom services have been provided at

Hospital pursuant to this Agreement. County shall cooperate with such authorized University personnel in such review.

7.0 INDEMNIFICATION

- 7.1. Each party shall indemnify, defend, and hold harmless the other party and its elected and appointed officers, employees and agents from and against any and all liability, including but not limited to demands, claims, actions, damages, fees, costs, and expenses (including attorney and expert witness fees), arising from or connected with the acts and/or omissions of the party providing the indemnification arising from and/or relating to this Agreement. Notwithstanding any other language set forth herein, the parties acknowledge and agree that neither University nor County shall be obligated to indemnify the other party with respect to the acts and/or omissions of Workforce Members. The parties both acknowledge that the obligation to indemnify does not extend to any other person or entity except as described above.
- 7.2. University shall use reasonable efforts to obtain agreements from all project sponsors indemnifying and holding harmless the County of Los Angeles from any and all liability for damages arising out of the performance of projects sponsored by them.

8.0 ADDITIONAL PROVISIONS

8.1. **Notices**. Unless otherwise specified in this Agreement, any notice, document, or other communication given or made hereunder shall be in writing and shall be deemed given upon (i) hand delivery or (ii) deposit of the same in the United States registered or certified mail, first-class postage and fee prepaid, and correctly addressed to the Party for whom it is intended at the following addresses:

If to County:

Chief Medical Officer County of Los Angeles Department of Health Services 313 North Figueroa Street, Room 908 Los Angeles, California 90012

with a copy to:

Office of the County Counsel Attn: Health Services Division 500 West Temple Street, 6th Floor Los Angeles, California 90012

Kathy K. Hanks, Director County of Los Angeles Department of Health Services Contracts and Grants Division 313 N. Figueroa St., 6th Floor East Los Angeles, CA 90012

If to University:

Keck School of Medicine University of Southern California Health Sciences Campus, KAM 500 Keith/Mayer Building 1975 Zonal Avenue Los Angeles, California 90033

with a copy to:

Office of the General Counsel University of Southern California Health Sciences Campus 1510 San Pablo HCC 600, MC9204 Los Angeles, CA 90033

or at such other place or places as may from time to time be specified in a notice similarly given. Each Party shall at all times keep the other Party notified of its current address and shall promptly notify the other Party of any change of address.

- 8.2. **Confidentiality.** Notwithstanding any other provision of this Agreement, University and County shall maintain the confidentiality of all records and information, including billings, University reports, audit reports, County records and patient records, as required by applicable Federal, State and local laws, ordinances, rules, regulations and directives (including County Department of Health Services' policy, and Hospital's Medical Staff Rules and Regulations with respect to Sponsored Program Services provided at Hospital) relating to confidentiality. University and County shall make reasonable efforts to inform all of their officers, employees, agents, independent contractors and others providing services hereunder of the confidentiality provisions of this Agreement.
- 8.3 **Compliance HIPAA.** The Parties acknowledge the existence of HIPAA and its implementing regulations. The Parties further understand that each has obligations as Covered Entities with respect to the confidentiality, privacy and security of patients' medical records and must take certain steps to preserve the confidentiality of this information both internally and externally. The Parties further acknowledge, as Covered Entities, each is independently accountable for the actions of their workforce, as well as the contents and enforcement of their Business Associates agreements. See 45 C.F.R. §§164.530(b)(e) and 164.504(e). In addition, the Parties acknowledge that they have entered into an Organized Health Care Arrangement and each is independently responsible to be HIPAA compliant. Pursuant to the terms of the Affiliation Agreement, each Party participates in a joint arrangement to provide integrated health care at County facilities.

<u>Liability for Violations of the HIPAA Privacy and Security Rule</u>. Hospital is responsible for compliance with HIPAA's Privacy and Security Rules, as well as that of their workforce which includes University staff performing approved Sponsored Program studies within the Hospital. As part of Hospital's workforce, Workforce Members personnel are obligated to promptly report noncompliance with the HIPAA Privacy or Security Rule to Hospital's HIPAA Privacy Officer. Workforce Members are not permitted to enter into any Business

Associate agreements or directly obtain a license with any vendor for the electronic exchange of protected health information ("PHI") without adhering to the County's contracting and approval process required for Hospital to adhere to HIPAA's Privacy and Security Rules.

8.4. Rules and Regulations

During the time that Workforce Members are at Hospital, such persons shall be subject to the rules and regulations of Hospital. The Director's administrator at Hospital shall furnish to University a copy of Hospital's rules and regulations which are applicable to University prior to the execution of this Agreement, and during the term of shall furnish University with any changes thereto as from time to time may be adopted. It is the responsibility of University to acquaint itself and such persons who may provide services hereunder with all such rules and regulations, as provided by Director's administrator at Hospital. Upon receipt of notice from County, University shall take such corrective action with respect to any Workforce Member who University determines after reasonable investigation does not comply with such rules and regulations; provided, however, that at the written request of County, University will permanently withdraw any of its Workforce Member, from the provision of services hereunder in the event that Director, in consultation with University, determines that: (1) any such Workforce Member has violated such rules or regulations, or (2) such Workforce Member's actions, while on County premises, indicate that such employee may adversely affect the delivery of health care services at the Hospital. Prior to requesting such removal, the Director must submit with such written notice a written statement of the facts supporting any such alleged violation or action and must reasonably consult with University to determine whether appropriate action should be taken. Nothing contained in this Agreement shall affect any rights which may be available to Workforce Members under University's IRB.

8.5. Reports and Documentation

- 8.5.1 County agrees to provide University and Sponsored Program Managers with timely notice of any adverse events involving County patients participating in Sponsored Programs.
- 8.5.2. County agrees that Hospital shall provide University with information concerning Hospital and participation by Hospital in Sponsored Programs as reasonably required by University to comply with applicable law or contractual obligations under Sponsor Agreements. Hospital shall further ensure that participation by County patients in Sponsored Programs is documented and records are maintained in accordance with applicable laws.
- 8.6. **Nondiscrimination in Services.** University shall not discriminate in the provision of services hereunder because of race, color, religion, national origin, ancestry, sex, age, sexual orientation, or physical or mental disability, in accordance with requirements of Federal and State law and County policy. University shall use reasonable efforts to ensure that intended beneficiaries of this Agreement are provided services without regard to race, color, religion, national origin, ancestry, sex, age, sexual orientation, or physical or mental disability.

8.7. **Nondiscrimination in Employment**

- 8.7.1. Nondiscrimination. University certifies and agrees that its policy is that all persons employed by it, its affiliates, subsidiaries or holding companies are and shall be treated equally by it without regard to, and shall not be discriminated against because of, race, color, religion, ancestry, national origin, sex, age, sexual orientation, or physical or mental disability, in compliance with all anti-discrimination laws and regulations of the United States of America and the State of California as they now exist or may hereafter be amended.
- 8.7.2. Employment Status. University shall make every effort to ensure it employs qualified applicants, and treats employees during employment, without regard to race, color, religion, ancestry, national origin, sex, age, sexual orientation, or physical or mental disability, nor shall University discriminate against such applicants or employees because of such characteristics; all in compliance with all applicable anti-discrimination laws and regulations of the United States of America and the State of California as they now exist or may hereafter be amended. Such action shall include the following: employment, upgrading, demotion, transfer, recruitment or recruitment advertising, lay-off or termination, rates of pay or other forms of compensation, and selection for training, including apprenticeship.
- 8.7.3. Vendors. University shall not discriminate against any subcontractor, bidder, or vendor on the basis of race, color, religion, ancestry, national origin, sex, age, sexual orientation, or physical or mental disability, as required by all applicable anti-discrimination laws and regulations of the United States of America and the State of California as they now exist or may hereafter be amended.
- 8.7.4. Verification. University shall allow County representatives access to its employment records during regular business hours upon advance written notice to verify compliance with these provisions when so requested by County. Prior to any such inspection, University may remove personal employee information from such records, which is protected under the privacy laws of the State of California. To the extent any such information may come into the possession of County during such an inspection, County hereby promises to protect same from disclosure to third parties.
- 8.7.5. Breach. Violation of any provisions under this §8.7 (nondiscrimination in employment) shall constitute an event of immediate termination pursuant to §5.4 (termination for cause) of this Agreement. County reserves the right to determine independently that the anti-discrimination provisions of this Agreement have been violated. A determination by the California Fair Employment Practices Commission or the Federal Equal Employment Opportunity Commission that University has violated State or Federal anti-discrimination laws or regulations shall constitute a finding by County that University has violated anti-discrimination provisions of this Agreement.
- 8.7.6 Any Sponsored Program Manager or designee conducting unauthorized Sponsored Programs are subject to immediate termination of such unauthorized Sponsored Programs, including revocation of Sponsored Program privileges at Hospital and

referral to the IRB, attending staff association, University or County leadership for corrective personnel action as appropriate.

- 8.8. **Workforce Member Performance While Under the Influence.** University shall use its reasonable efforts to ensure that none of its Workforce Members shall perform services hereunder while under the influence of any alcoholic beverage, medication, narcotic or other substance that might impair his or her physical or mental performance.
- 8.9. University Performance during Disaster or Civil Unrest. University recognizes that health care facilities maintained by County, including shelters and relief facilities operated by County during a disaster, provide care essential to the population of the communities they serve and that these services are of particular importance at the time of a natural disaster or other similar event, or at the time of a riot, insurrection or civil unrest. Notwithstanding any other provision of this Agreement, University shall continue to provide services at County facilities during any natural disaster or other similar event, riot, insurrection or civil unrest, so long as such performance remains physically possible and does not subject Workforce Members to unreasonable threat to personal safety. Failure to comply with this requirement shall be considered an event of termination for cause pursuant to §5.4 (termination for cause) of this Agreement. Parties shall work together to develop a plan for the provision of services in the event of a disaster or civil unrest.
- 8.10. Licenses, Permits, Registrations and Certificates. University and County, respectively, shall obtain and maintain during the Term all appropriate licenses, permits, registrations and certificates required by law for the provision of their respective services hereunder. University shall require that all its Workforce Members, including all its independent contractors, who perform services hereunder obtain and maintain in effect during the Term, all licenses, permits, registrations and certificates required by law which are applicable to their performance hereunder. Copies of all such licenses, permits, registrations and certifications shall be made available to County or University, respectively, upon request.
- 8.11. **Unlawful Solicitation.** University shall inform all of its officers, employees and agents, including all its independent contractors, providing services hereunder in writing of the provisions of Article 9 of Chapter 4 of Division 3 (commencing with Section 6150) of the Business and Professions Code of the State of California (i.e., State Bar Act provisions regarding unlawful solicitation as a runner or capper for attorneys) and shall use reasonable efforts to ensure that there is no violation of said provisions by its officers, employees, agents and independent contractors. University agrees that if a patient requests assistance in obtaining the services of any attorney, it shall use reasonable efforts to refer the patient to the attorney referral services of all those bar associations within County of Los Angeles or the appropriate County agency that have such a service.

A copy of such written notice shall be retained by University for purposes of inspection and audit and made available to County upon reasonable written request.

8.12. **Conflict of Interest.** No County officer or employee whose position in County enables him or her to influence the award of this Agreement or any competing agreement and/or no officer, employee, agent, or independent contractor of University who may financially benefit from the provision of services hereunder shall in any way participate in County's approval process for the award of this Agreement or any competing agreement, or ongoing

evaluation of such services, under this Agreement or any competing agreement, or in any way attempt to unlawfully influence County's approval or ongoing evaluation of such services.

University shall comply with all conflict of interest laws, ordinances and County regulations now in effect or hereafter to be enacted during the Term. University represents that it is not now aware of any facts which create a conflict of interest. If University hereafter becomes aware of any facts which might reasonably be expected to create a conflict of interest, it shall promptly make a full written disclosure of such facts to County. Full written disclosure shall include, without limitation, identification of all persons involved and a complete description of all relevant circumstances.

8.13. Representation against Contingent Fees

- 8.13.1. Representation. University represents that no person or selling agency has been employed or retained to solicit or secure this Agreement upon an agreement or understanding for a commission, percentage, brokerage or contingent fee, excepting bona fide employees or bona fide established commercial or selling agencies maintained by University for the purpose of securing business.
- 8.13.2. Remedy. Breach or violation of this representation shall constitute an event of termination for cause, pursuant to §5.4 (termination for cause). In addition to the remedies provided in this Agreement, County in its sole discretion shall be permitted to deduct from payments made under this Agreement, or otherwise recover, the full amount of such commission, percentage, brokerage or contingent fee.
- 8.14. **Delegation and Assignment.** Neither University nor County shall delegate its duties or assign its rights hereunder, either in whole or in part, without prior written consent of the other Party. Any delegation or assignment which does not have such consent shall be null and void. For purposes of this §8.14 (delegation and assignment), consent shall require a written amendment to this Agreement which is formally approved and executed by the Parties. Any billings to County by any delegate or assignee on any claim under this Agreement, absent County's consent, shall not be paid by County.
- 8.15. **Subcontracting.** No performance of this Agreement, or any portion thereof, shall be subcontracted by either Party without the prior written consent of the other Party, as provided in this §8.15 (subcontracting). Any attempt by either Party to subcontract any performance, obligation, or responsibility under this Agreement, without the prior written consent of the other Party, shall be null and void and shall constitute an event of immediate termination pursuant to §5.4 (termination for cause) of this Agreement. Each Party shall notify all of its potential subcontractors of the provisions of this §8.15 (subcontracting).
 - 8.15.1. County Approval. If University desires to subcontract any portion of its performance, obligations or responsibilities under this Agreement, University shall make a written request to County for written approval to enter into the particular subcontract. County will review University's request to subcontract and determine, in its sole discretion, whether or not to consent to such request on a case-by-case basis. The Director or his or her designee is hereby authorized to act for and on

behalf of County pursuant to this §8.15.1 (County approval), including consenting to any subcontracting. University's request to County shall include:

- 8.15.1.1. The reason(s) for the particular subcontract.
- 8.15.1.2. A detailed description of the work to be performed by the proposed subcontractor.
- 8.15.1.3. Identification of the proposed subcontractor and an explanation of why and how the proposed subcontractor was selected.
- 8.15.1.4. A draft copy of the proposed subcontract.
- 8.15.1.5. Unless otherwise determined unnecessary by County, copies of certificates of insurance and performance security from the proposed subcontractor shall be provided to Hospital to ensure that the subcontractor maintains all the programs of insurance required by §2.20 (insurance coverage requirements).
- 8.15.1.6. Any other information or certifications requested by County.
- 8.15.2. Approved Subcontracting. Notwithstanding any County consent to any subcontracting, University shall remain responsible for any and all performance required of it under this Agreement, including the obligation to properly supervise, coordinate, and perform all work required hereunder. No subcontract shall bind or purport to bind County. Further, County approval of any subcontract shall not be construed to limit in any way University's performance, obligations, or responsibilities to County, nor shall such approval limit any of County's rights or remedies contained in this Agreement.
 - 8.15.2.1. Bound by Agreement. In the event that County consents to any subcontracting, the subcontractor, on behalf of itself, its successors and administrators, shall assume and be bound by and shall be deemed to have assumed and agreed to be bound by each and all of the provisions of this Agreement and any amendment hereto.
 - 8.15.2.2. Consent. In the event that County consents to any subcontracting, such consent shall apply to each particular subcontract only and shall not be, nor construed to be, a waiver of this §8.15.2. (consent) or a blanket consent to any further subcontracting. Hospital providing such consent does not confer Business Associate nor agency relationship between Hospital and subcontractor.
 - 8.15.2.3. Liability. University shall be solely liable and responsible for any and all payments and other compensation to all subcontractors and their officers, employees, and agents. County shall have no liability or responsibility whatsoever for any payment or other compensation for any subcontractors or their officers, employees and agents.

- 8.15.2.4. Copies. University shall deliver to County a fully executed copy of each subcontract entered into by University pursuant to this §8.15 (subcontracting), on or immediately after the effective date of the subcontract but in no event later than the date any work is performed under the subcontract.
- 8.16. **Compliance with Laws and Regulations**. All Sponsored Programs done by University and County shall comply with all applicable Federal, State, and local laws, ordinances, rules, governmental regulations, guidelines and directives applicable to its performance hereunder, including without limitation current National Institutes of Health guidelines.

8.17. Governing Law, Jurisdiction, and Venue

8.17.1. **Governing Law**; **Entire Agreement**. This Agreement shall be governed by and construed in accordance with the law of the State California without reference to its choice-of-law doctrines. This Agreement, and any other documents executed in connection herewith by authorized representatives of the Parties, contain the entire agreement between the Parties relating to the subject matter contained herein, and supersede all prior or contemporaneous agreements, written or oral, with respect thereto.

8.18. Construction

To the extent there are any rights, duties, obligations, or responsibilities enumerated in the recitals or otherwise in this Agreement, they shall be deemed a part of the operative provisions of this Agreement and are fully binding upon the Parties.

8.19. Conflict of Terms

To the extent that there exists any conflict or inconsistency between the language of this Agreement and that of any Exhibit(s), Attachment(s), and any other documents incorporated herein by reference, the language found within this Agreement shall govern and prevail.

8.20. Alteration of Terms

The body of this Agreement and any Exhibit(s), and/or Attachment(s) attached hereto, fully expresses all understandings of the parties concerning all matters covered and shall constitute the total Agreement

No addition to, or alteration of, the terms of this Agreement, whether by written or verbal understanding of the Parties, their officers, employees or agents, shall be valid and effective unless made in the form of a written amendment to this Agreement as set forth in §8.22, which is formally approved and executed by the Parties and delivered to the other Party in the same manner as this Agreement.

8.21. **Dispute Resolution**.

The Parties agree to work together to jointly resolve any perceived dispute or issue regarding a Sponsored Program Manager's activity or conduct and shall attempt to resolve any dispute

arising out of or relating to this Agreement through negotiations between the representatives of both Parties or their respective designees, who have authority to settle the issue. Such informal process may be initiated, by either Party, by written notice given by the initiating Party to the other Party in accordance with the provisions set forth in §8.1 (notices). Nothing herein is intended to foreclose any other rights under Agreement that each Party may have to terminate or suspend this Agreement.

- 8.21.1 Individual Sponsored Program Manager's breaches will be evaluated on a case-by-case basis to determine if the Sponsored Program Manager's Sponsored Program should be terminated.
- 8.21.2 Repeated or persistent patterns of egregious Sponsored Program Manager's breaches will result in termination of the either the Sponsored Program and/or the Sponsored Program Manger's right to conduct a Sponsored Program at the Hospital.

8.22. Amendments

- 8.22.1. For any change which affects the Term, payments, or any term or condition included under this Agreement, an amendment shall be prepared by County and then executed by University and by the Governing Board or its authorized designee.
- 8.22.2. The Governing Board or CEO or designee may require the addition and/or change of certain terms and conditions in the Agreement during the Term, County reserves the right to add and/or change such provisions as required by the Governing Board, CEO or designee. To implement such changes, an amendment to the Agreement shall be prepared by County and then executed by University and by the Director.
- 8.22.3. The reimbursement rates may be adjusted upon agreement by both Parties.
- 8.22.4. The Director may require, at his/her sole discretion, the addition and/or change of certain terms and conditions in the Agreement to conform to changes in federal or state law or regulation, during the Term. County reserves the unilateral right to add and/or change such provisions as required by law, regulation, without the need for University's written consent, to preserve this Agreement's conformity and compliance to federal and state law or regulation. To implement such changes, an amendment to the Agreement shall be prepared by County and then executed by the Parties.
- 8.23. **Authorization Warranty.** Both Parties hereby represent and warrant that the person executing this Agreement on behalf of such Party is an authorized agent who has actual authority to bind that Party to each and every term, condition, and obligation set forth in this Agreement and that all requirements of such Party have been fulfilled to provide such actual authority.
- 8.24. **Fair Labor Standards.** University shall comply with all applicable provisions of the Federal Fair Labor Standards Act and shall indemnify County for any violations of this obligation, pursuant to §7.0 (indemnification) of this Agreement.

- 8.25. **Employment Eligibility Verification.** Each Party warrants that it fully complies with all Federal statutes and regulations regarding employment of aliens and others, and University warrants that the temporary personnel which it refers to County facilities hereunder, including all independent University personnel performing services hereunder, meet the citizenship or alien status requirements contained in Federal statutes and regulations. Each Party shall obtain, from all of its personnel performing services hereunder, all verification and other documentation of employment eligibility status required by Federal statutes and regulations as they currently exist and as they may be hereafter amended. Each Party shall retain such documentation for all such personnel for the period prescribed by law. University shall indemnify County for any violations of this obligation, pursuant to §7.0 (indemnification) of this Agreement.
- 8.26. **Restrictions on Lobbying.** If any Federal monies are to be used to pay for University's services under this Agreement, University shall comply with all certifications and disclosure requirements prescribed by Section 319, Public Law 101-121 (31 U.S.C. § 1352) and any implementing regulations, and shall ensure that each of its subcontractors receiving funds provided under this Agreement also fully comply with all such certifications and disclosure requirements.
- 8.27. **County Lobbyists.** University and each County lobbyist or County lobbying firm, as defined in County of Los Angeles Code Section 2.160.010, retained by University, shall fully comply with the County Lobbyist Ordinance, County of Los Angeles Code Chapter 2.160. Failure on the part of University or any County lobbyist or County lobbying firm retained by University to fully comply with the County Lobbyist Ordinance shall constitute an event of immediate termination pursuant to §5.4 (termination for cause) of this Agreement.

8.28. County's Child Support Compliance Program

- 8.28.1. University's Warranty of Adherence to County's Child Support Compliance Program: University acknowledges that County has established a goal of ensuring that all individuals who benefit financially from County through contract are in compliance with their court-ordered child, family, and spousal support obligations in order to mitigate the economic burden otherwise imposed upon County and its taxpayers. As required by County's Child Support Compliance Program (County Code Chapter 2.200) and without limiting University's duty under this Agreement to comply with all applicable provisions of law, University warrants that it is now in compliance and shall during the Term maintain in compliance with employment and wage reporting requirements as required by the federal Social Security Act [(42 USC section 653 (a)] and California Unemployment Insurance Code section 1088.55, and shall implement all lawfully served Wage and Earnings Withholdings Orders or Child Support Services Department (ACSSD) Notices of Wage and Earnings Assignment for Child, Family, or Spousal Support, pursuant to Code of Civil Procedure section 706.031 and Family Code section 5246 (b).
- 8.28.2. <u>Termination for Breach of Warranty to Maintain Compliance with County's Child Support Compliance Program</u>: Failure of University to maintain compliance with the requirements set forth in §8.28.1 (University's warranty of

adherence to County's child support compliance program), shall constitute an event of termination for cause pursuant to §5.4 (termination for cause) under this Agreement. Without limiting the rights and remedies available to County under any other provision of this Agreement, failure of University to cure within ninety (90) calendar days of written notice shall be grounds upon which County may terminate this contract pursuant to §5.4 (termination for cause) of this Agreement and pursue debarment of University, pursuant to County Code Chapter 2.202.

- 8.29. **Merger and Integration Provision.** All exhibits, attachments and addenda to this Agreement are incorporated herein. This Agreement fully expresses all understandings of the Parties concerning all matters covered and shall constitute the entire agreement of the Parties, superseding the prior contract between the Parties regarding its subject matter. No addition to or alteration of the terms of this Agreement, whether by written or oral understanding of the Parties, their officers, agents or employees, shall be valid unless made in the form of a written amendment to this Agreement which is formally approved and executed by the Parties.
- 8.30. **Severability.** If any provision of this Agreement, including all the exhibits, attachments and addenda hereto, or the application thereof to any person or circumstance, is held to be illegal or invalid, the remainder of the Agreement and the application of such provision to other persons or circumstances shall not be affected, except as otherwise provided in this §8.30 (severability). If such invalidation has the effect of materially altering the obligations of either Party, then the Parties shall diligently seek to amend the Agreement to restore the prior balance of obligations. If the Parties are unable to agree on such amendment within forty-five (45) days following notice of the invalidation, then the impaired Party may deem the invalidation an event of termination for cause under §5.4 (termination for cause), without fault of or breach by either Party.
- 8.31. **Investigations**. Each Party shall cooperate regarding outside investigations of the other Party as reasonably requested by the other Party as it relates to this Agreement. If any government agency undertakes an investigation of a Party, the other Party shall comply with that Party's reasonable request to make available information and records in connection with the investigation. Compliance with this provision by either Party shall not constitute a waiver of the attorney-client privilege.
- 8.32. **No Third Party Beneficiaries.** None of the provisions of this Agreement are or shall be construed as for the benefit of or enforceable by any person not a Party to this Agreement.
- 8.33. **Waiver**. No waiver, express or implied, of any breach of this Agreement, shall constitute a waiver of any right under this Agreement or of any subsequent breach, whether of a similar or dissimilar nature. All of the rights or remedies permitted or available to a Party under this Agreement, or at law or in equity, shall be cumulative and not alternative, and the exercise of any right or remedy shall not constitute a waiver or election of remedies with respect to any other permitted or available right or remedy.
- 8.34. **Section References**. Throughout this Agreement, each section reference includes any subsection.

8.35. Contractor Responsibility and Debarment.

- 8.35.1. A responsible contractor is a contractor who has demonstrated the attribute of trustworthiness, as well as quality, fitness, capacity, and experience to satisfactorily perform the contract. It is County's policy to conduct business only with responsible contractors.
- 8.35.2. University is hereby notified that, in accordance with Chapter 2.202 of the County Code, if County acquires information concerning the performance of University on this or other agreements which indicates that University is not responsible, County may, in addition to other remedies provided under the Agreement, debar University from bidding or proposing on, or being awarded, and/or performing work on County agreements for a specified period of time not to exceed three (3) years, and terminate any or all existing agreements University may have with County
- 8.35.3. County may debar University if the Governing Board finds, in its discretion, that University has done any of the following: (1) violated a term of an agreement with County or a nonprofit corporation created by County, (2) committed any act or omission which negatively reflects on University's quality, fitness, or capacity to perform an agreement with County, or engaged in a pattern or practice which negatively reflects on same, (3) committed an act or offense which indicates a lack of business integrity or business honesty, or (4) made or submitted a false claim against County or any other public entity.
- 8.35.4. If there is evidence that University may be subject to debarment, the Department will notify University in writing of the evidence which is the basis for the proposed debarment and will advise University of the scheduled date for a debarment hearing before County's Hearing Board.
- 8.35.5. County's Contractor Hearing Board will conduct a hearing where evidence on the proposed debarment is presented. University shall be given an opportunity to submit evidence at that hearing. After the hearing, the Contractor Hearing Board shall prepare a tentative decision, which shall contain a recommendation regarding whether University should be debarred, and, if so, the appropriate length of time of the debarment. University and the Department shall be provided an opportunity to object to the tentative proposed decision prior to its presentation to the Governing Board.
- 8.35.6. After consideration of any objections, or if no objections are submitted, a record of hearing, the proposed decision, and any other recommendation of the Contractor Hearing Board shall be presented to the Governing Board. The Governing Board shall have the right to modify, deny, or adopt the proposed decision and recommendation of the Contractor Hearing Board.
- 8.35.7. These terms shall also apply to subcontractor(s) or Business Associates of University.

8.36. **Use of Recycled-Content Bond Paper**. Consistent with the Governing Board's policy to reduce the amount of solid waste deposited at County landfills, University agrees to use recycled-content paper to the maximum extent possible in connection with the services to be performed by University under this Agreement

8.37. Compliance with Jury Service Program:

- 8.37.1. Jury Service Program: This Agreement is subject to the provisions of the County's ordinance entitled Contractor Employee Jury Service ("Jury Service Program") as codified in Sections 2.203.010 through 2.203.090 of the County Code.
- 8.37.2. Written Employee Jury Service Policy:
 - 8.37.2.1. Unless University has demonstrated to County's satisfaction either that University is not a "contractor" as defined under the Jury Service Program (Section 2.203.020 of the County Code) or that University qualifies for an exception to the Jury Service Program (Section 2.203.070 of the County Code), University shall have and adhere to a written policy that provides that its employees shall receive from University, on an annual basis, no less than five (5) days of regular pay for actual jury service served. University's policy may further provide that employees deposit any fees received for such jury service with University or that University deduct from the employee's regular pay the fee received for jury service.
 - For purpose of this Section, and as set forth in the Jury Service 8.37.2.2. Program provision of the County Code as described hereinabove: "contractor" shall mean a person, partnership, corporation, or other entity, that has a contract with County, or a subcontract with a County contractor, and has received, or will receive, an aggregate sum of Fifty Thousand Dollars (\$50,000) or more in any twelve (12) month period under one (1) or more County contracts or subcontracts; "employee" shall mean any California resident who is a full-time employee of University; and "full-time" shall mean forty (40) hours or more worked per week, or a lesser number of hours, if: a) the lesser number is a recognized industry standard as determined by County, or b) University has a long-standing practice that defines the lesser number of hours as full-time. Full-time employees providing short-term temporary services of ninety (90) days or less within a twelve (12) month period are not considered full-time for purposes of the Jury Service Program. If University uses any subcontractor to perform services for County under this Agreement, the subcontractor shall also be subject to the provisions of this Section. The provisions of this Section shall be inserted into any such subcontract agreement and a copy of the Jury Service Program shall be attached to such subcontract agreement.

- 8.37.2.3. If University is not required to comply with the Jury Service Program on the Effective Date of this Agreement, University shall have a continuing obligation to review the applicability of its "exception status" from the Jury Service Program, and University shall immediately notify County if University at any time either comes within the Jury Service Program's definitions of "contractor", or if University no longer qualifies for an exception to the Jury Service Program. In either event, University shall immediately implement a written policy consistent with the Jury Service Program. County may also require, at any time during the Term, and at its sole discretion, that University demonstrate to County's satisfaction that University either continues to remain outside of the Jury Service Program's definition of "contractor" and/or that University continues to qualify for an exception to the Jury Service Program. University and its subcontractors, if applicable, may demonstrate their exemption, or compliance, with the above subject Jury Service Program by completing a "County of Los Angeles Contractor Employee Jury Service Program Application for Exemption and Certification Form" which should be obtained from, and returned to, the Director within ten (10) calendar days before the Effective Date of this Agreement.
- 8.37.2.4. University's violation of this Section of the Agreement may constitute a material breach of this Agreement. In the event of such breach, County may, in its sole discretion, terminate this Agreement and/or bar University from the award of future County contracts for a period of time consistent with the seriousness of the breach.
- 8.38. **Notice to Employees Regarding the Safely Surrendered Baby Law.** University shall notify and provide to its employees, and shall require each subcontractor to notify and provide to its employees, a fact sheet regarding the Safely Surrendered Baby Law, its implementation in Los Angeles County, and where and how to safely surrender a baby. The fact sheet is set forth in English and Spanish and is also available on the Internet at www.babysafela.org for printing purposes."
- 8.39. University's Acknowledgment of County's Commitment to the Safely Surrendered Baby Law. University acknowledges that County places a high priority on the implementation of the Safely Surrendered Baby Law. University understands that it is the County's policy to encourage all County contractors to voluntarily post County's "Safely Surrendered Baby Law" poster in a prominent position at University's place of business. University will also encourage its subcontractors, if any, to post this poster in a prominent position in the subcontractor's place of business. County's Department of Children and Family Services will supply University with the poster to be used."

8.40. University's Warranty of Compliance with County's Defaulted

8.40.1. University acknowledges that County has established a goal of ensuring that all individuals and businesses that benefit financially from County through contract are

- current in paying their property tax obligations (secured and unsecured roll) in order to mitigate the economic burden otherwise imposed upon County and its taxpayers.
- 8.40.2. Unless University qualifies for an exemption or exclusion, University warrants and certifies that to the best of its knowledge it is now in compliance, and during the Term will maintain compliance, with Los Angeles Code Chapter 2.206.
- 8.41. **Time Off for Voting**. University shall notify its employees, and shall require each subcontractor to notify and provide to its employees, information regarding the time off for voting law (Elections Code Section 14000). Not less than ten (10) days before every statewide election, University and its subcontractors shall keep posted conspicuously at the place of work, if practicable, or elsewhere where it can be seen as employees come or go to their place of work, a notice setting forth the provisions of Section 14000.
- 8.42 **Use of Name and Trademarks.** Except as required by law or permitted by this Agreement, neither Party shall use the name, logo, trademark, or symbol of the other Party or its affiliates in any advertising or promotional material without the prior written consent of the other Party.

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IN WITNESS WHEREOF, Governing Board has caused this Agreement to be executed by the Director and University has caused this Agreement to be executed in its behalf by its duly authorized officer, the day, month, and year first above written.

COUNTY OF LOS ANGELES

	By: Mitchell H. Katz, M.D. Director of Health Services			
	THE UNIVERSITY OF SOUTHERN CALIFORNIA			
	By: Signature			
	Printed Name			
	Title			
APPROVED AS TO FORM:				
Mark Saladino County Counsel				
ByPrincipal Deputy County Counsel				